

## **REMARKS**

In view of the amendments and remarks that follow, Applicants respectfully submit that the application is in condition for allowance. Accordingly, applicants request reconsideration of the application, withdrawal of the rejections of record and issuance of a Notice of Allowance.

Claims 1-16 are pending in the application. Claims 1-10 stand rejected for the reasons of record and Claims 11-16 have been withdrawn from consideration as drawn to a non-elected invention. Claims 1, 2, 3 and 8 have been amended to put them in condition for allowance. The amendments are not considered to involve the addition of new matter and entry thereof is respectfully requested.

It is noted and acknowledged that the references cited in the Information Disclosure Statements filed on 10/22/2003 and 03/11/2004 have been made of record.

### **Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 1-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that any claim not specifically rejected is rejected as being dependent on a rejected claim.

In particular, in Claim 1, the Office considers the recitation of the term "prodrug" to be indefinite. While disagreeing that the word "prodrug" is indefinite, Claim 1 has been amended to delete the term "prodrug" in order to expedite the prosecution of the claims.

In Claim 2, the recitation of the phrase "to convert the benzylic alcohol to the phenol" is considered to lack antecedent basis and renders the claim indefinite. Applicants have amended Claim 2 to recite "Compound 2 to Compound 3". This amendment is considered to overcome this ground of rejection.

Claims 1 and 2 are also rejected as indefinite because they recite a process for making a genus of a compound of formula I but the process steps shown appear to be

limited to species. Applicants have amended Claim 1 by limiting the process to a genus of compounds clearly supported by the specification. Applicants submit that this overcomes this ground of rejection.

Claim 3 is rejected because recitation of the phrase "with a nucleophile to afford compound of 8" renders the claim indefinite as it is not clear how any nucleophile would result in the final product 8. Claim 3 has been amended to replace the term "a nucleophile" with "compound 14". This amendment is considered to be supported by the specification and entry thereof is respectfully requested.

Claim 10 is rejected because the Office notes that the structural makeup of pyridinium chloride or pyridinium iodide remains unknown. Applicants respectfully traverse this rejection and provide the following comments. Attached are some pages from Lancaster research chemicals 2004-2005 catalog showing that pyridinium chloride is also called Pyridine hydrochloride. On page 136 of the catalog, the structure of pyridine hydrochloride is shown. Either name can be used however, it is clear that the structure is not unknown. Applicants respectfully request that this ground of rejection be withdrawn.

Claim 8 is rejected because the use of plurals in steps d and e is considered confusing. Applicants have amended the claim to put the term in the singular tense.

Applicants submit that the amendments to the claims have overcome the rejections under 35 U.S.C. § 112, second paragraph. Withdrawal of this ground of rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for making compounds or salts of the claimed compounds, does not reasonably provide enablement for making prodrugs of the claimed compounds. The Office has summarized the factors to be considered in making an enablement rejection and concluded that the claims are not enabled.

Applicants disagree that the specification does not provide any direction. One skilled in the art would be able to use the teachings referred to in the specification to make the claimed prodrugs. However, while disagreeing with the Office's conclusion, Claim 1, as noted above, has been amended to delete the term "prodrug" in order to expedite the prosecution of the claims.

Claims 1-7 are also rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for making compounds or salts of the claimed compounds, does not reasonably provide enablement for making solvates of the claimed compounds.

Applicants disagree that the specification does not provide any direction. Clearly one skilled in the art would be able to use the knowledge in the art to prepare solvates of the instantly claimed compounds.

However, while disagreeing with the Office's conclusion, Claim 1 has been amended to delete the term "solvates" in order to expedite the prosecution of the claims.

Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for process of making compound of formula I or compound 10 wherein step b) involves addition of alkylmagnesium halide (Grignard reagent) to COOR<sub>6</sub>, does not reasonably provide enablement for process of making compound of formula I or compound 10 with any other alkylating agent as generically recited in claim 1 and 3. Additionally, the process claim 8 while being enabling for process of making compound of formula 14 wherein step b) involves reaction of the nucleophile derived from ethylacetacetate, does not reasonably provide enablement for process of making compound of formula 11 with any nucleophile leading to the compound of formula 14 as generically recited in claim 8.

The Office goes on to conclude, after considering a number of factors, that undue experimentation would be required to practice Applicants' invention.

Applicants respectfully traverse the rejection and provide the following comments. Claims 1, 3 and 8 have been amended to limit the scope of the alkylating agent as noted in the specification and the action. While disagreeing that one skilled in the art would not be able to use additional alkylating agents not specifically named in the specification, Applicants have amended the claims to that subject matter that one skilled in the art would be reasonably expected to be able to make without undue experimentation.

In view of the foregoing, Applicants submit that the application, as amended, is in condition for allowance and courteously solicit a Notice of Allowance.

If any fee due is not accounted for herein, please charge such fee to Deposit Account No. 19-3880. If any extension of time is required and not petitioned for, such extension is hereby petitioned for, and it is requested that any fee due in connection therewith be charged to the aforementioned Deposit Account.

The foregoing response is believed to be fully responsive to the outstanding Office Action. If a direct personal communication would advance the prosecution of this application, please contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,



Elliott Korsen  
for Applicants  
Reg. No. 32,705

Date: February 7, 2005  
Bristol-Myers Squibb Company  
Patent Department  
P.O. Box 4000  
Princeton, NJ 08543-4000  
(609) 252-4741